PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: CELAL ALBAYRAK	Examiner: SHENGJUN WANG
Serial No.: 10/028,258	Group Art Unit: 1617
Filed: DECEMBER 19, 2001	Docket No. ABS0005/US/2
For: INDUCED PHASE TRANSITION METHOD FOR THE PRODUCTION OF MICROPARTICLES CONTAINING HYDROPHILIC ACTIVE AGENTS	

Mail Stop AP
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. 81.132

Dear Sir or Madam:

I, Dr. CELAL ALBAYRAK, hereby state the following:

A. BACKGROUND

1. I am a citizen of Germany, and reside in Berlin, Germany.

2. I am a named inventor of the above captioned patent application.

B. EXPERIMENTAL

1. I have reviewed the proposed amendment to provide the generic description of the materials corresponding to certain trade names as required in the outstanding Final Office Action.

2. The generic terminology for the trademarks as set forth in the proposed amendment accurately reflects the identity of the materials sold under these names. This identity is notoriously known in the art for these trade names as follows:

"Resomer®" (polylactide polymers and copolymers)

"Poloxamer®" (polyethylene-polypropylene glycol surfactant),

"Poloxamine®" (polyalkoxylated symmetrical block polymers of ethylene diamine surfactant), and ,

"Pluronic® F68" (surfactants which are block copolymers based on ethylene oxide and propylene oxide).

3. This assertion is supported by the attached copies of relevant Internet pages showing that the generic terminology as recited above does in fact correspond to the indicated trade names. These trade names and the chemical description corresponding to the generic description of these materials are well known to the skilled artisan for that reason.

C. CONCLUSION

1. Based upon my experience in this art, and in view of the facts presented above, it is my conclusion that the proposed added generic description reflects the conventionally understood materials that would be associated with the corresponding trademarks by the skilled artisan, and therefore does not introduce new information to the application. Thus, per the requirement of the outstanding Advisory Action, I state that the assorted chemicals in the proposed amendment consist of the same materials under the trade names.

D. DECLARATION

I further believe that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

DATE: 29.11.2006 SIGNATURE: [signature]

91748

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Opinion concerning Corrections in entries of poloxamers, meroxapols and poloxamines, and respective nomenclature conventions adopted by the plenary session of the SCCNFP on 17 February 1999

Introduction

The present opinion refers to the need of corrections to be made in 48 entries of the Inventory of ingredients employed in cosmetic products, published in 1996 (OJ L132, 1-6-1996) belonging to the group of mixed block polymers denominated by convention as Poloxamers and Meroxapols. These corrections are required according to the rules of transparency, as imposed in Cosmetics Directive 76/768/EEC.

However, the above corrections are closely related to a requirement for appropriate Nomenclature Conventions, which actually do not exist for the said Poloxamers and Meroxapols, while the existing ones concerning the Polyethylene and Polypropylene Glycol homo- and co-polymers are inadequate and confusing. Namely, the only existing such conventions No. 35 and 36, mentioned in the Inventory, plus the No. 39 (recently proposed for the first update) are framed below.

> **35.** Alkoxylated materials are named by including the alkoxylation level as the average number of moles of ethylene oxide and/or propylene oxide.
>
> **36.** Ethoxylated alcohols are named by completing the conventional alcoholic stem name with "eth" followed by the average number of moles of ethylene oxide.
>
> **39.** The term "Alkoxynol-n" means an ethoxylated alkyl phenol where n indicates the average number of ethylene oxide units.
>
> When the name is: the alkyl is:
>
> octoxynol : tetramethybutyl
>
> nonoxynol : nonyl
>
> dodoxynol : dodecyl or *tributyl* (*trialkyl phenol derivative*)
>
> pentadoxynol : pentadecyl

The deletions in the frame indicate that the corresponding cosmetic ingredients do not exist (at least in the Inventory, and in the INCI Dictionary as well). Neither Polyethylene Glycol followed by parenthetical notation, nor branched chain nonoxyols, dodoxynol and pentadoxynols, while one of the dodoxynols is a trialkyl (not alkyl) phenol derivative.

The numerous other classes of homo- and co-polymers mentioned below (with the suggested nomenclature conventions) are not noticed at all, neither in the existing, nor in the proposals for the first update nomenclature conventions.

Additional Nomenclature Conventions **(for the first update of the Inventory)**

1. Polyethylene glycol homopolymers are named by the acronymial abbreviation PEG followed by the number of ethylene-oxide monomer units, e.g. PEG-10.

Their ether- or ester derivatives are named according to the common rules applicable in the respective ethylene glycol derivatives, by replacing 'ethylene glycol' by 'PEG-n' e.g. PEG-10 Stearate, PEG-10 Cetyl Ether).

Especially, for the ethoxylated alcohols (e.g. PEG-10 Cetyl Ether) an alternative denomination may be used, consisting from the conventional alcoholic stem name with

the ending "eth", followed by the ethylene-oxide monomer units (e.g. Deceth-10 is the alternative of PEG-10 Decyl Ether).

2. Polypropylene glycol homopolymers are named by the acronymial abbreviation PPG followed by the number of isopropylene-oxide monomer units, e.g. PPG-12.

Their ether- or ester derivatives are named according to the common rules applicable in the respective propylene glycol derivatives, by replacing 'propylene glycol' by 'PpG-n' e.g. PPG-12 Stearate, PPG-12 Cetyl Ether).

The rule 35 is an application of this alternative nomenclature of PEG-derivatives.

3. PEG and PPG polymers or their derivatives in which one of the terminal primary alcoholic groups (-CH_2OH) has been oxidized to carboxy group (-COOH) are named by adding the term "carboxylic acid" to the parent name of the original polymer, e.g. PEG-10 Carboxylic Acid, Coceth-7 Carboxylic Acid, Ammonium Laureth-8 Carboxylate.

4. Copolymers of ethylene and propylene glycols are denominated by mixed names, such as PPG-n-PEG-m, where n and m denote the average number of the respective monomer units "randomly bound" to each other. (Non-random, i.e. 'block copolymers' are assigned special denominations, according to rules 6-8 below).

5. The term 'Poloxamer' denotes a symmetrical block copolymer, consisting of a core of PPG polyoxyethylated to both its terminal hydroxyl groups, i.e. conforming to the general type $(PEG)_x$-$(PPG)_y$-$(PEG)_x$. Each Poloxamer name is followed by an arbitrary code number, according to the average numerical values of the respective monomer units denoted by X and Y in the above general type.

The average molar ratio of ethylene oxide to isopropylene oxide (2X : Y) monomer units (derived form oxirane and 2-methyl-oxirane respectively) is cited at the end of the Chem./Iupac name of the respective Poloxamer species.

6. The term 'Meroxapol' denotes a symmetrical block copolymer, consisting of a core of PEG polyoxypropylated to both its terminal hydroxyl groups, i.e. conforming to the general type $(PPG)_x$-$(PEG)_y$-$(PPG)_x$. Each Meroxapol name is followed by an arbitrary code number, according to the average numerical values of the respective monomer units denoted by X and Y in the above general type.

The average molar ratio of isopropylene oxide to ethylene oxide (2X : Y) monomer units (derived form 2-methyl-oxirane and oxirane respectively) is cited at the end of the Chem./Iupac name of the respective Meroxapol species.

7. The name 'Poloxamine' denotes polyalkoxylated symmetrical block polymers of ethylene diamine conforming to the general type

$[(PEG)_x$-$(PPG)_y]_2$-NCH_2CH_2N-$[(PPG)_y$-$(PEG)_x]_2$

Each Poloxamine name is followed by an arbitrary code number, according to the average numerical values of the respective monomer units denoted by X and Y in the above general type.

The average molar ratio of ethylene oxide to isopropylene oxide (4X : 4Y) monomer units (derived form oxirane and 2-methyl-oxirane respectively) is cited at the end of the Chem./Iupac name of the respective Poloxamer species.

8. Aziridine homopolymers (polyethylene imines) are named using the acronymial abbreviation PEI followed by the average number of the ethylene-imine monomer units, e.g. PEI-30.

9. Polyethoxylated and/or polypropoxylated silicone polymers are named copolyols, e.g. DIMETHICONE COPOLYOL (Siloxanes and silicones, di-me, hydroxy-terminated, ethoxylated propoxylated)

Required Corrections in the Inventory

In the first row of the following Tables 1 to 3 it is cited, as example, the monograph of the INCI Dictionary, corresponding to the entry of the Inventory just following it in the Table, in order to show that the molar ratio of monomer units cited in parentheses at the end of the Chem./Iupac name in the Inventory (4th column) is not correct ; instead of molar ratio, it gives the X:Y ratio of the general formula which is unknown to the reader of the Inventory. Obviously, these numerical ratios must be corrected, as already indicated in the respective nomenclature convention above, i.e. in order to correspond either to 2X:Y (in the Tables 1-2), or to 4X:4Y (in the Table 3).

However, for the Poloxamers and Meroxapols there is an additional factor of lacking transparency, namely the selected as Chem./Iupac names, which in both cases obey to the rubric "Oxirane, methyl-, polymer with oxirane". Certainly, these rubric names are not the best selection, being quite unsuitable to serve the role of the Inventory. Although they represent one of the solutions adopted by the Chemical Abstracts' services in order to

simplify their indexing problems, these denominations are neither IUPAC names, nor even real chemical names. They substitute the chemical name by citing the reagents, from which the polymer is produced (and this only theoretically, because the reagents practically used are not always the same). In any case, a better selection is required. For instance: the Poloxamers may be expressed as "Symmetrical block polymers of poplypropylene glycol (core) with polyethylene glycol terminal chains" and the Meroxapols as"Symmetrical block polymers of poplyethylene glycol (core) with polypropylene glycol terminal chains".

TABLE 1 : Poloxamers

POLOXAMER 101

Definition: Poloxamer 101 is the polyoxyethylene, polyoxypropylene block polymer that conforms generally to the formula:

in which the average value of x, y and z are respectively 2, 16 and 2.

	INCI Name	CAS N°	Chem/IUPAC Name	Function
001	POLOXAMER 101	9003-11-6	Oxirane, methyl-, polymer with oxirane (2;16)	emulsifers / surfactants
002	POLOXAMER 105	9003-11-6	Oxirane, methyl-, polymer with oxirane (11;16)	emulsifers / surfactants
003	POLOXAMER 105 BENZOATE			emulsifers
004	POLOXAMER 108	9003-11-6	Oxirane, methyl-, polymer with oxirane (46;16)	emulsifers / surfactants
005	POLOXAMER 122	9003-11-6	Oxirane, methyl-, polymer with oxirane (5;21)	emulsifers / surfactants
006	POLOXAMER 123	9003-11-6	Oxirane, methyl-, polymer with oxirane (7;21)	emulsifers / surfactants
007	POLOXAMER 124	9003-11-6	Oxirane, methyl-, polymer with oxirane (11;21)	emulsifers / surfactants
008	POLOXAMER 181	9003-11-6	Oxirane, methyl-, polymer with oxirane (3;30)	emulsifers / surfactants
009	POLOXAMER 182	9003-11-6	Oxirane, methyl-, polymer with oxirane (8;30)	emulsifers / surfactants
010	POLOXAMER 182 DIBENZOATE			emulsifers
011	POLOXAMER 183	9003-11-6	Oxirane, methyl-, polymer with oxirane (10;30)	emulsifers / surfactants
012	POLOXAMER 184	9003-11-6	Oxirane, methyl-, polymer with oxirane (13;30)	emulsifers / surfactants
013	POLOXAMER 185	9003-11-6	Oxirane, methyl-, polymer with oxirane (19;30)	emulsifers / surfactants
014	POLOXAMER 188	9003-11-6	Oxirane, methyl-, polymer with oxirane (75;30)	emulsifers / surfactants
015	POLOXAMER 212	9003-11-6	Oxirane, methyl-, polymer with oxirane (8;35)	emulsifers / surfactants

016	POLOXAMER 215	9003-11-6	Oxirane, methyl-, polymer with oxirane (24;35)	emulsifers / surfactants
017	POLOXAMER 217	9003-11-6	Oxirane, methyl-, polymer with oxirane (52;35)	emulsifers / surfactants
018	POLOXAMER 231	9003-11-6	Oxirane, methyl-, polymer with oxirane (6;39)	emulsifers / surfactants
019	POLOXAMER 234	9003-11-6	Oxirane, methyl-, polymer with oxirane (22;39)	emulsifers / surfactants
020	POLOXAMER 235	9003-11-6	Oxirane, methyl-, polymer with oxirane (27;39)	emulsifers / surfactants
021	POLOXAMER 237	9003-11-6	Oxirane, methyl-, polymer with oxirane (62;39)	emulsifers / surfactants
022	POLOXAMER 238	9003-11-6	Oxirane, methyl-, polymer with oxirane (97;39)	emulsifers / surfactants
023	POLOXAMER 282	9003-11-6	Oxirane, methyl-, polymer with oxirane (10;47)	emulsifers / surfactants
024	POLOXAMER 284	9003-11-6	Oxirane, methyl-, polymer with oxirane (21;47)	emulsifers / surfactants
025	POLOXAMER 288	9003-11-6	Oxirane, methyl-, polymer with oxirane (122;47)	emulsifers / surfactants
026	POLOXAMER 331	9003-11-6	Oxirane, methyl-, polymer with oxirane (7;54)	emulsifers / surfactants
027	POLOXAMER 333	9003-11-6	Oxirane, methyl-, polymer with oxirane (20;54)	emulsifers / surfactants
028	POLOXAMER 334	9003-11-6	Oxirane, methyl-, polymer with oxirane (31;54)	emulsifers / surfactants
029	POLOXAMER 335	9003-11-6	Oxirane, methyl-, polymer with oxirane (38;54)	emulsifers / surfactants
030	POLOXAMER 338	9003-11-6	Oxirane, methyl-, polymer with oxirane (128;54)	emulsifers / surfactants
031	POLOXAMER 401	9003-11-6	Oxirane, methyl-, polymer with oxirane (6;67)	emulsifers / surfactants
032	POLOXAMER 402	9003-11-6	Oxirane, methyl-, polymer with oxirane (13;67)	emulsifers / surfactants
033	POLOXAMER 403	9003-11-6	Oxirane, methyl-, polymer with oxirane (21;67)	emulsifers / surfactants
034	POLOXAMER 407	9003-11-6	Oxirane, methyl-, polymer with oxirane (98;67)	emulsifers / surfactants

TABLE 2 : Meroxapols

MEROXAPOL 105

Definition: Meroxapol 105 is the polyoxypropylene, polyoxyethylene block polymer that conforms generally to the formula:

in which the average values of x, y and z are respectively 7, 22 and 7.

	INCI Name	CAS N°	Chem/IUPAC Name	Function
001	MEROXAPOL 105	9003-11-6	Oxirane, methyl-, polymer with oxirane (7;22)	emulsifers / surfactants
002	MEROXAPOL 108	9003-11-6	Oxirane, methyl-, polymer with oxirane (7;91)	emulsifers / surfactants
003	MEROXAPOL 171	9003-11-6	Oxirane, methyl-, polymer with oxirane (12;4)	emulsifers / surfactants
004	MEROXAPOL 172	9003-11-6	Oxirane, methyl-, polymer with oxirane (12;9)	emulsifers / surfactants
005	MEROXAPOL 174	9003-11-6	Oxirane, methyl-, polymer with oxirane (12;23)	emulsifers / surfactants
006	MEROXAPOL 178	9003-11-6	Oxirane, methyl-, polymer with oxirane (12;136)	emulsifers / surfactants
007	MEROXAPOL 251	9003-11-6	Oxirane, methyl-, polymer with oxirane (18;6)	emulsifers / surfactants
008	MEROXAPOL 252	9003-11-6	Oxirane, methyl-, polymer with oxirane (18;14)	emulsifers / surfactants
009	MEROXAPOL 254	9003-11-6	Oxirane, methyl-, polymer with oxirane (18;34)	emulsifers / surfactants
010	MEROXAPOL 255	9003-11-6	Oxirane, methyl-, polymer with oxirane (18;51)	emulsifers / surfactants
011	MEROXAPOL 258	9003-11-6	Oxirane, methyl-, polymer with oxirane (18;163)	emulsifers / surfactants
012	MEROXAPOL 311	9003-11-6	Oxirane, methyl-, polymer with oxirane (21;7)	emulsifers / surfactants
013	MEROXAPOL 312	9003-11-6	Oxirane, methyl-, polymer with oxirane (21;15)	emulsifers / surfactants
014	MEROXAPOL 314	9003-11-6	Oxirane, methyl-, polymer with oxirane (21;39)	emulsifers / surfactants

TABLE 3 : Poloxamines

POLOXAMINE 304

Definition: Poloxamine 304 is the polyoxyethylene, polyoxypropylene block polymer of ethylene diamine that conforms to the formula:

In which the values of x and y are respectively 4 and 3.

INCI Name	CAS N°	Chem/IUPAC Name	Function

001	POLOXAMINE 304	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (4:3)	emulsifers
002	POLOXAMINE 504	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (8:7)	emulsifers
003	POLOXAMINE 701	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (12:2)	emulsifers
004	POLOXAMINE 702	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (13:4)	emulsifers
005	POLOXAMINE 704	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (14:12)	emulsifers
006	POLOXAMINE 707	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (19:47)	emulsifers
007	POLOXAMINE 901	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (18:2)	emulsifers
008	POLOXAMINE 904	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (19:16)	emulsifers
009	POLOXAMINE 908	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (22:122)	emulsifers
010	POLOXAMINE 1101	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (21:3)	emulsifers
011	POLOXAMINE 1102	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (21:7)	emulsifers
012	POLOXAMINE 1104	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (21:19)	emulsifers
013	POLOXAMINE 1301	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (25:3)	emulsifers
014	POLOXAMINE 1302	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (26:8)	emulsifers
015	POLOXAMINE 1304	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (26:24)	emulsifers

016	POLOXAMINE 1307	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (23:74)	emulsifers
017	POLOXAMINE 1501	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (30:4)	emulsifers
018	POLOXAMINE 1502	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (30:10)	emulsifers
019	POLOXAMINE 1504	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (32:28)	emulsifers
020	POLOXAMINE 1508	11111-34-5	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis (propanol) (22:122)	emulsifers

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